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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,485	04/19/2004	Makarand P. Gore	200315628-1	3286

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EXAMINER

MERCIER, MELISSA S

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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03/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/827,485	Applicant(s) GORE, MAKARAND P.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 19-44, 47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 45 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is Melissa Mercier. Contact information is provided at the end of this Office Action.

Summary

Receipt of Applicants Remarks and Amended Claims filed on January 25, 2008 is acknowledged. Claims 1-49 remain pending in this application. Claims 19-44 and 47-49 remain withdrawn as reading on non-elected subject matter. Claims 1-18 and 45-46 remain under prosecution in this application.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

The rejection of claim 46 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been withdrawn in view of Applicants Amendment to the claims correcting the lack of antecedent basis for the term encapsulated.

The rejection of claim 16 under 35 U.S.C. 103(a) as being unpatentable over Backlund et al. (US 6,004,580) in view of Kabalnov (US 6,432,183), has been withdrawn, as no specific teaching in the references meet the limitation of the claim.

Maintained Rejections

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-10, 13, 15, and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Backlund et al. (US 6,004,580).

Backlund teaches a pharmaceutical composition containing a micro emulsion made up of a hydrophilic component, a lipophilic component, a surfactant and a drug (abstract). The drug is dissolved in either the hydrophilic or the lipophilic component of the micro emulsion (abstract). The preferred hydrophilic component is water or a mixture of water and a pharmaceutically acceptable solvent (column 4, lines 55-61).

Regarding claim 2-3, Backlund also teaches that their o/w micro emulsions are suitable carriers for cyclosporin, a Water-insoluble immunosuppressant (col. 6, lines 12-17). The micro emulsions taught by Backlund can be either the oil-in-water or water-in-oil type (Fig. 1; col. 2, lines 21-36).

Regarding claim 5, suitable lipophilic components include castor oil and soybean oil (col. 4, lines 62-67).

Regarding claim 6-7, alcohols are also disclosed as amphiphilic co-solvents (column 5, lines 66-67). Applicant has identified alcohols to be "removable oils". Alcohols are also known to evaporate when heated; therefore, the disclosure of an addition of an alcohol would meet the limitations of claim 6.

Art Unit: 1615

Regarding claims 10 and 15, pharmaceutically acceptable surfactants include lecithins, which are edible surfactants (col. 5, lines 47-53). If the surfactant does not have two hydrocarbon chains like lecithin, a salt and a co-surfactant, such as a short-chain alcohol, must be added (col. 2, lines 9-13).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11-12 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Backlund et al. (US 6,004,580) in view of Woo (Formulation and physicochemical properties of macro- and micro emulsions prepared by interracial ion-pair formation between, see IDS).

The teachings of Backlund are discussed above and applied in the same manner.

Backlund, does not teach the use of or amount to use of a surfactant comprising an ion-pair formation between an amino acid and a fatty acid, wherein the amino acid comprises L-arginine or L-lysine and the fatty acid comprises stearic acid or oleic acid.

Woo teaches that water-in-oil and oil-in-water emulsions can be prepared using stearic acid and L-arginine or L-lysine (pg. 105-109).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the components taught by Woo to emulsify the composition taught by Backlund because these naturally occurring fatty acids and amino acids

Art Unit: 1615

are extremely safe and ideal for pharmaceutical use (Woo, pg. 103). Furthermore, determining result effective amounts of the ingredients beneficially taught by the cited references is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the ordinary artisan.

Response to Arguments

Applicant's arguments filed January 25, 2008 have been fully considered but they are not persuasive. Applicant argues Backlund teaches away from the claimed "jettable solution, wherein said solution has a viscosity sufficiently low that said solution is dispersed by jetting through a jetting fluid dispenser", based on the teachings of the micro emulsions being made into gels.

The Examiner respectfully disagrees with Applicants conclusions based on Applicants own definition of what would constitute a jettable solution. On pages 3-4 of the instant specification, jettable is defined as "any material that has properties sufficient to all the material to allow the material to be selectively deposited by any digitally addressable inkjet material dispenser". As recited in the rejection under 112, 2nd paragraph above, Applicant has not recited a specific viscosity which would be "sufficiently low" in the rejected claims. Furthermore, Applicant has not recited specific dispensers and their delivery mechanisms, (such as high pressure); therefore, the rejection is maintained.

Applicant further argues Backlund does not disclose a "jettable solution" as recited in claim 45 or a means for emulsifying said pharmaceutical payload into a jettable solution". Again, the examiner respectfully disagrees for the same reasons as

Art Unit: 1615

discussed supra. Backlund does disclose the micro emulsion is prepared by mixing the components together. Since Applicant has not identified what the "means for emulsifying" comprises, the disclosure of mixing is deemed to meet the limitation of the instant claims.

Newly Applied Rejections/Objections

Claim Objections

Claim 3 is objected to because of the following informalities: a comma appears to be missing between peptides and an antimicrobial in line 2. Appropriate correction is required.

Claim 8 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The term "aqueous" requires that water is present as a solvent. The terminology appears to be redundant. Correction is requested.

Claim 15 is objected to because of the following informalities: a comma appears to be missing between biocide and a viscosity modifier in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1615

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 and 45-46 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1, the claim recites "wherein said solution has a viscosity sufficiently low that said solution is dispersed by jetting through a jetting fluid dispenser". The specification does not describe what would be "sufficiently low" to allow for a jetting. The ability to be dispersed by jetting would also be dependent upon the pressure at which the fluid is dispensed as well as the temperature. It is suggested that if support is present in the specification, Applicant amend the claims to recite a specific viscosity of the solution, such as those recited in claim 16.

Further regarding claim 1, it is unclear what a "naturally occurring oil" would comprise. Applicant has limited said oil to castor oil, an oleic acid and an oleyl alcohol, coconut oil, mineral oil, cottonseed oil, squalene, safflower oil, and a fatty ester. It appears Applicant is attempting to claim oils derived from natural sources and not "naturally occurring oils".

Regarding claims 3 and 10, M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and

Art Unit: 1615

formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

The specification does not describe any species of the instantly claimed derivatives of a water insoluble peptide, an antimicrobial, a PPI, a calcium channel blocker, a beta blocker, an anesthetic, a steroid, an antioxidant, a rennin inhibitor, an alkaloid, a cystostatica, an anti coagulant, a lipid regulating agent, an antidepressant, a neuroleptic, an immunosuppressant, an immunomodulator, an antibiotic, an anti-inflammatory agent, nicotinamide derivatives at p. 11, therefore, it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by derivatives thereof.

Regarding claim 6, the specification has not provided adequate written description for the limitation "wherein said removable oil is configured to be evaporated under the influence of heat or vacuum". A review of the specification did not disclose how "removable oil" can be structurally altered or configured to be evaporated.

Regarding claim 14, the specification has not provided adequate written description for the limitation "edible solvent comprises a salt". A review of the specification did not disclose what types of solvents might comprise a salt.

Regarding claim 15, Applicant has not provided adequate written description for "a non-acrylic polymer". After a review of the specification, the Examiner was unable to

Art Unit: 1615

locate any species of polymers that Applicant feels would provide adequate written description for the very broad claim of "a non-acrylic polymer". If Applicant believes such support exists, they are invited to identify such support in the specification as originally filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 45-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites removable oil. It is unclear to the Examiner what oils would fall under a "removable oil". A review of the specification on page 9 appears to define a removable oil to be an aliphatic alcohol, a cyclic alcohol, terpenes, aromatic side chain alcohols, ketones and esters. However, it is unclear to the Examiner how these are considered oils. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 033 (Fed. Cir. 1999). The term "removable oil" in claim 1 is used by the claim to mean "alcohol", while the accepted meaning is "a substance that is viscous in its liquid state at ambient temperatures or slightly warmer and is both hydrophobic and

Art Unit: 1615

lipophilic.” The term is indefinite because the specification does not clearly redefine the term. Clarification is requested.

The term “edible aqueous solution” is also unclear to the Examiner. It is unclear what additional components are required to be in the solution. Clarification is requested.

Claim 1 further recites a pharmaceutical. It would appear that Applicant is referring to a pharmaceutically active agent; however, the Examiner has not been able to locate a definition in the specification. Clarification is requested. For purposes of examination, the Examiner has interpreted it to be an active agent or drug.

Regarding claims 3 and 10, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 6, it is unclear to the Examiner how removable oil can be configured to be evaporated. It appears that Applicant is attempting to evaporate the “removable oil” out of the solution as is. However, the claim recites that the oil must be “configured” to be removed. Clarification is requested.

Claim 10 contains the trademark/trade name Pluronic. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not

Art Unit: 1615

identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe ethylene oxide and propylene oxide block copolymers, and, accordingly, the identification/description is indefinite.

Regarding claim 14, it is unclear to the Examiner what would constitute an edible solvent comprising a salt. It is unclear what kind of solvents would fit into such a description. Clarification is requested. It appears that Applicant is attempting to further limit the solvent to further comprise a salt.

Regarding claim 17, it is unclear what Applicants is claiming by "a pharmaceutical release rate of said solution is varied by varying said naturally occurring oil". It is unclear what the metes and bounds of "varied by varying" is. It is unclear if the amount of the oil is altered.

Regarding claim 18, it is unclear if the 15% soy bean oil by volume, and 74% aqueous solution, is in addition to the oil and aqueous solution already present in claim 1 or if it is the oil and aqueous solution of claim 1. Clarification and correction is requested.

Regarding claims 45-46, the word "means" is preceded by the word(s) "for emulsifying" and "for stably dispersing" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Art Unit: 1615

Further regarding claims 45-46, it is unclear what Applicant is claiming by “pharmaceutical payload”. After a review of the specification, the examiner was unable to locate what would be encompassed by a pharmaceutical payload. The examiner has interpreted it to be any pharmaceutically active component.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-25, 8, 13-15, and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Owen et al. (US Patent 5,633,226).

Owen discloses a water in oil micro emulsion which readily converts to an oil in water emulsion by addition of aqueous fluid to the water in oil micro emulsion (abstract).

The biologically active material composition comprises:

1. an aqueous phase;
2. a pharmaceutically acceptable oil;
3. an oil dispersible surfactant;
4. a water soluble biologically active material;

Additional adjuvant such as stabilizers, coloring agents (claim 15), oil soluble drugs (claim 2) and the like may be added. Each component is disclosed as being

Art Unit: 1615

suitable for use in the subject and will usually be food grade and/or pharmaceutically acceptable (column 4, lines 49-59).

The water in oil micro emulsions can be liquids at room temperature (column 5, lines 9-11). It is the position of the Examiner that a liquid would have a viscosity sufficiently low to allow for "jetting" as recited in the claims.

The aqueous phase ranges up to 60% by volume, the oil phase is from about 5-99% by volume, and the surfactant is present from about 1-70% by volume (column 5, lines 16-19).

Regarding claim 5, the oil can include edible oils, such as coconut oil (column 6, lines 27-35).

Regarding claim 13-14, the aqueous phase may comprise other solvents, such as polyhydric alcohols, glycerol, and propylene glycol (column 5, lines 45-48). Salts can also be present, such as when saline is employed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dennis et al. (US Patent 6,623,765).

Due to the new grounds of rejection presented in this office action, this action is made Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is

Art Unit: 1615

(571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615